CHARTER
DoD PHARMACY AND THERAPEUTICS COMMITTEE

I. AUTHORITY

The National Defense Authorization Act for Fiscal Year 2000, Public Law 106-65, Oct. 5, 1999, Section 701, amended Chapter 55 of Title 10, United States Code, by inserting after Section 1074f a new section, 1074g, entitled Pharmacy benefits program. Under Section 1074g(b), the Secretary of Defense is required to establish a Pharmacy and Therapeutics Committee for the purpose of developing a uniform formulary of pharmaceutical agents, review such formulary on a periodic basis, and make additional recommendations regarding the formulary as the committee determines necessary and appropriate The committee shall function under procedures established by the Secretary under regulations promulgated to implement this section.

II. DoD PHARMACY AND THERAPEUTICS COMMITTEE

A GENERAL PROVISIONS

The Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee (henceforth, P&T Committee) is responsible for development and maintenance of a uniform formulary. It consists of government members whose primary mission and goal is to uniformly, consistently and equitably provide appropriate drug therapy to meet patients' clinical needs in an effective, efficient and fiscally responsible manner with the objective of encouraging the use of safe, effective pharmaceutical agents that will produce the desired outcomes of drug therapy at a reasonable cost to DoD.

B PROCEDURES

The uniform formulary shall assure the availability of pharmaceutical agents in the complete range of therapeutic classes. The selection for inclusion on the uniform formulary of particular pharmaceutical agents shall be based on the relative clinical effectiveness and cost effectiveness of the agents in each therapeutic class of pharmaceutical agents.

1. Clinical Effectiveness· The P&T Committee shall presume a pharmaceutical agent is included in a therapeutic class of the uniform formulary This presumption shall exist unless the P&T Committee finds by majority vote that the agent does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcomes over other drugs included on the uniform formulary in that therapeutic class. If the P&T Committee makes such finding, the P&T Committee may recommend that the pharmaceutical agent be excluded from a therapeutic class of the uniform formulary

2. Cost Effectiveness: The P&T Committee, in evaluating the cost effectiveness of pharmaceutical agents, shall evaluate the cost of agents in a therapeutic class in relation to the safety, effectiveness, and clinical outcomes of such agents. If the P&T Committee determines by majority vote that a pharmaceutical agent in a therapeutic class is not cost effective in relation to the safety, effectiveness, and clinical outcome of such agent, the P&T Committee may recommend that the agent be excluded from the therapeutic class of the uniform formulary. The approving authority shall rely on the evaluation by the P&T Committee as it relates to cost effectiveness.

3. Basic Core Formulary The Basic Core Formulary (BCF) is a sub-set of the approved uniform formulary and applies only to military treatment facilities (MTFs). The Basic Core Formulary is the minimum formulary that must be available at all MTFs. Pharmaceutical agents recommended for approval for the uniform formulary may also be recommended for inclusion or exclusion on the Basic Core Formulary.

4. All recommendations shall be by majority vote of the voting members

C. DUTIES OF THE DoD PHARMACY AND THERAPEUTICS COMMITTEE

1. Consider the relative safety, effectiveness, cost, and other pertinent factors in deciding which pharmaceutical agents are included on the uniform formulary and BCF

2 Periodically conduct therapeutic drug class reviews.

3. Review Military Health System (MHS) pharmacy utilization and cost data.

4. Consider Medical Readiness implications pertaining to BCF issues.

5. Review and approve the contracting strategies and evaluation factors for DoD and joint VA/DoD pharmaceutical procurement contracting initiatives, and prospectively identify circumstances where it would be medically necessary to use a non-contracted drug in lieu of a contracted drug.

6 Monitor the effectiveness of the MHS drug distribution system

7. Identify drugs that are candidates for prior authorization and recommend prior authorization criteria that would be applied across the MHS.

8. Evaluate requests for changes to the uniform formulary and the BCF from the Military Health System and will develop a standard procedure for submission of requests.

9 Consider other matters related to the Uniform Formulary and MHS drug distribution system

D MEMBERSHIP

The P&T Committee members must have expertise in identifying the medical and pharmaceutical needs of the populations served throughout the Military Health System The P&T Committee will have 19 voting members and additional non-voting members as outlined below A physician selected by the Director, TRICARE Management Activity will chair the P&T Committee

1. Voting Members
   a. Physician Chairman (HA/TMA).

   b. Director, DoD Pharmacy Programs, TRICARE Management Activity (TMA).

   c. Director, DoD Pharmacoeconomic Center (PEC) (recorder).

   d. The Army, Navy and Air Force Surgeons General (SG) Internal Medicine specialty consultants or designees

   e. One Army, Navy or Air Force SG Pediatric specialty consultant* or designee

   f. One Army, Navy or Air Force SG Family Practice specialty consultant* or designee.

   g. One Army, Navy or Air Force SG Obstetric/Gynecology specialty consultant* or designee.

   h One physician or pharmacist from the United States Coast Guard

   i The Army, Navy, and Air Force Pharmacy specialty consultants or designee.

   j. The Contracting Officer's Representative (COR) for the TRICARE Mail Order Pharmacy (TMOP) program

   k The Contracting Officer Representative (COR) for the TRICARE Retail Pharmacy (TRRx) Program.

   l. One physician or pharmacist from the Department of Veterans Affairs (VA)

m One provider at large from the Army, Navy and Air Force

*The Pediatric, Family Practice and Obstetric/Gynecology positions on the P&T Committee will be rotated among the Services every 3 years

2 Non-Voting Members

a Representative(s) from Joint Readiness Clinical Advisory Board (JRCAB).

b Representative(s) from the TMA Office of General Counsel.

c Representative(s) from the TMA Resource Management Directorate.

d. Representative(s) from the Defense Supply Center Philadelphia (DSCP)

3. Voting members should be available to serve on the P&T Committee for a minimum of two years.

4 Additional subject matter experts may be requested to participate as required to address specific drugs and/or therapeutic classes under review.

5. The DoD P&T Committee will meet quarterly as scheduled by the Chairman. Meetings will be scheduled far enough in advance to facilitate appropriate scheduling and notice of Formulary Beneficiary Advisory Panel (BAP) meetings.

E SUPPORTING AGENCY

The TRICARE Management Activity will provide administrative and related support to the P&T Committee.

III. AGENDA & ROUTING OF MINUTES

The agenda will be provided to the P&T Committee members not later than (NLT) 7 days prior to the meeting date. P&T Committee meeting minutes will be forwarded, to the Director, DoD Pharmacy Programs, TMA, no later than 21 days after the meeting The BAP will be provided opportunity to comment on the recommendations contained within the P&T Committee minutes. The P&T Committee minutes, with its recommendations, along with the comments of the BAP will then be forwarded to the Executive Director, TMA, for final decision.

IV. DURATION OF CHARTER:

The TMA Deputy Director will review this charter biennially from the date of approval

APR - 1 2004

V. DATE CHARTER IS FILED:

William Winkenwerder, Jr., MD